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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,856

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KIT-387

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EXAMINER

LE, HOA T

ART UNIT

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1794

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,856	Applicant(s) KOKUBO ET AL.	
	Examiner H. T. Le	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>July 2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it contains more than one paragraph. An abstract should be limited to a single paragraph. See MPEP 608.01(b). In addition, an abstract should not be referred to a drawing unless it cannot be understood without a reference to a drawing. It is also suggested that no paragraph numbering should be used in an abstract because the content of the specification may be amended (e.g. addition or deletion of paragraphs) which would render the number of the paragraph on an abstract out of sequence and thus create unnecessary confusion. Correction is required.

Claim Rejections - 35 USC § 112

2. Claims 1-19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 15, it is unclear what is meant by "pseudo-single domain". The term "pseudo" is vague and thus the scope of the claimed invention cannot be ascertainable.

Other claims are deemed indefinite in view of their dependency upon either claim 1 or claim 15.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 15 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14 and 15 of U.S. Patent No. 10/523,738. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method of making exothermic elements by heating in a reducing atmosphere. See also page 10, third paragraph of the conflicting application.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-19 are rejected under 35 U.S.C. 102(a) or (b) as anticipated by the prior art discussed in the instant specification at page 2, paragraph [0008]; that is, the Article entitled "Ceramics for Treatment of Cancer", Chemical Industry, Vol. 52, No. 5, 2001.

The article teaches a material for cancer treatment comprising silica microsphere coated with a ferromagnetic. The material is expected to be exothermic because it comprises the same core and coating components as claimed. The microspheres have a diameter of 25 μm . The coating comprises crystal grains with a diameter of 50 nm and numerous cracks. The method is the same as claimed; that is, heating in a reducing atmosphere. See Applicant's own specification, page 2, paragraph [0008]. As admitted by Applicant, the only difference between the claimed invention and the prior art is that the deposition reaction of iron hydroxide, as taught in the prior art, is unstable (See instant specification at paragraph [0011]). With regard to the product claims 1-14, although the process as taught by the prior art is inferior as argued by Applicant, the process taught in the prior art yields the same product as that of the claimed invention as discussed above. With regard to the method claims 15-19, the unstable reaction of the coating is not relevant to the claimed invention because the feature that would provide stable reaction (to differentiate from that of the prior art) is not present in the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-9 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al (US 4,177,253).

Claim 1: Davies teaches magnetic particles comprising a core and a coating of ferromagnetic layer. See col. 1, lines 23-28. The magnetic particles are used for immunoassay. The use of the magnetic particles for hyperthermic treatment as recited in claims is a recitation of an intended use which does not amount to any patentable difference. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In the alternative, one of ordinary skill in the art would have found it obvious to apply the magnetic particles as taught by Davies for hyperthermic treatment since such use has been known in the art (for example, the WO'publication WO'597 or the article entitled "Ceramics for treatment of cancer" as cited by applicant).

Claims 2-9, 13 and 14: The core comprises silica (col. 4, lines 36-40), has a spherical form with a diameter within the claimed range (col. 4, lines 44-50). The coating comprises crystal grains of magnetic iron oxide (col. 5, lines 1-14).

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Claims 15-19: The method of forming magnetic particles by heating in a reducing atmosphere is taught at col. 5, lines 15-54. Therefore, gamma hermatite is expected to form after the heating treatment. Heating at between 100 to 500°C is taught at col. 5, lines 54-61.

9. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al (US 4,177,253) as applied to claims 1-9 and 13-19 above, and further in view of the Japanese publication JP 11-191,509 ("JP'509").¹

Davies teaches the claimed magnetic particles as featured in claims 1-9 and 13-19 as discussed above. JP'509 teaches a metal oxide coating on magnetic particles as drug delivery carrier. Therefore, one of ordinary skill in the art would have been motivated to further coat the coated magnetic particles of Davies with a metal oxide layer as taught by JP'509 in order to optimize the drug delivery properties of the magnetic particles.

10. Claims 1-9, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Japanese publication JP 8-119,635 ("JP'635") in view of the WO publication 99/33597 ("WO'597") and the Japanese publication JP 6-245993 ("JP'993").²

The JP'635 discloses a method of making granular magnetite particles using a granular goethite fine particle powder containing silicon compound for precursor particles. Therefore, it is necessarily inherent that the granular magnetic fine particles

¹ Cited by Applicant.

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having the same properties (i.e. exothermic) and coated structure as claimed. The WO'597 teaches a method of making magnetic alloy powder having a single magnetic domain particle size and reduced cracking. Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of JP'635 and WO'597 to produce magnetite particles with reduced cracking on the surface of the particles. The JP'993 teaches the application of magnetic composition in hyperthermia treatment. Therefore, one of ordinary skill in the art would have been motivated to apply the product resulted from the combined teachings of JP'635 and WO'597 in hyperthermia treatment as taught by JP'993.

11. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP'635, WO'597 and JP'993 as applied to claims 1-9 and 13-19 above, and further in view of the Japanese publication JP 11-191,509 ("JP'509").³

JP'635, WO'597 and JP'993 teach the claimed magnetic particles as featured in claims 1-9 and 13-19 as discussed above. JP'509 teaches a metal oxide coating on magnetic particles as drug delivery carrier. Therefore, one of ordinary skill in the art would have been motivated to further coat the coated magnetic particles as taught by JP'993, JP'635 and WO'597 with a layer of metal oxide as taught by JP'509 in order to optimize the drug delivery properties of the magnetic particles.

12. Other references are cited as art of interest.

² Cited by Applicant.

³ Cited by Applicant.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. T. Le whose telephone number is 571-272-1511. The examiner can normally be reached on 9:30 a.m. to 6:00 p.m., Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Thi Le/
H. (Holly) T. Le
Primary Examiner
Art Unit 1794

August 31, 2008